

Wisconsin Public Psychiatry Network Teleconference (WPPNT)

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Transcranial Magnetic Stimulation: TMS

A proven non-drug treatment for depression

Presented by:
Dr. Leslie Taylor, MD
& Ian Cox

TMS Center of Madison

- Opened in January of 2013
- Collaboration between Rosecrance and Connections Counseling



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NEURONETICS

Understanding the Problem

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NEURONETICS

Major Depression: A Large Patient Population Currently Being Underserved



16.1 Million
US Adults with MDD



7.2 Million Treated



4.5 Million
Poorly Served



Lack of efficacy

Intolerable side effects

Kessler RC et al. *JAMA*. 2003;289(23):3095-3105.; 2012 United States Census Bureau, <<http://www.census.gov>>

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NEURONETICS

Top 10 Causes of Disability A Major Burden for Society Today

1. Lower Respiratory Infections
2. Diarrheal
- ➡ 3. **Unipolar Major Depression**
4. Ischemic Heart Disease
5. HIV/AIDS
6. Cerebrovascular Disease
7. Premature Birth
8. Birth Trauma
9. Road Traffic Accidents
10. Neonatal Infections

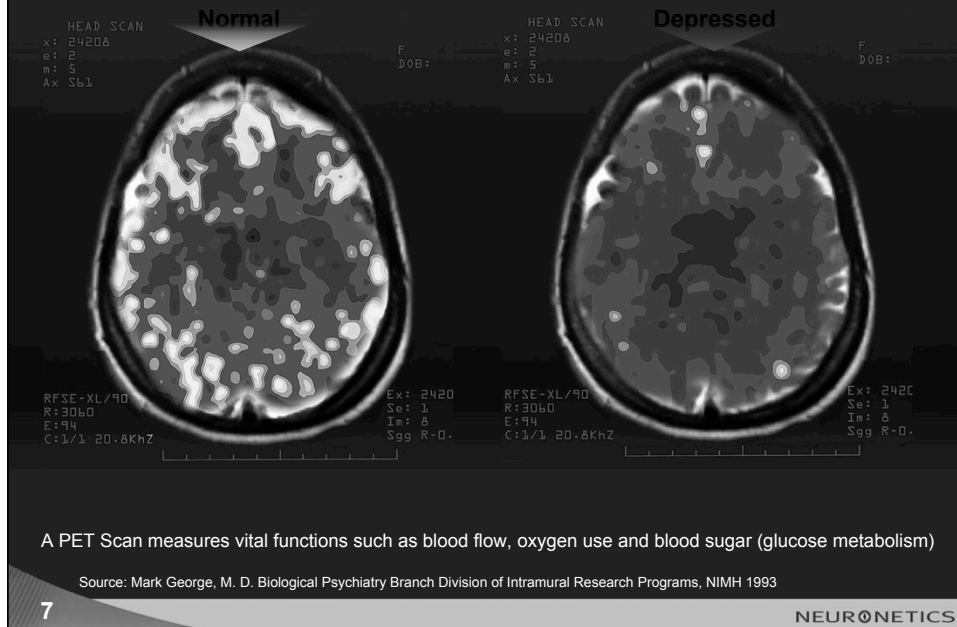


The World Health Organization. The World Health Report 2004: Changing History, Annex Table 3:
Burden of disease in DALYs by cause. Geneva: WHO, 2004.

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NEURONETICS

Brain Activity is Reduced in Depression



Repeated Activation of Left Prefrontal Cortex is Known to Produce Antidepressant Effects

- Neuroimaging studies have documented changes in functional connectivity between tissue directly stimulated by NeuroStar TMS and in deep brain regions known to be involved in mood regulation

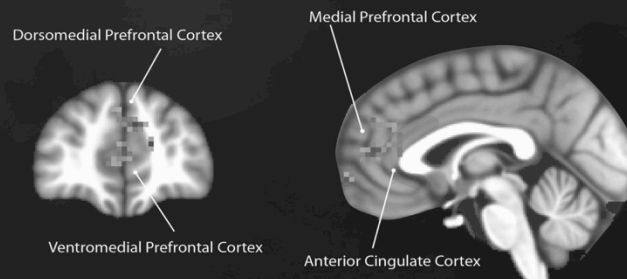
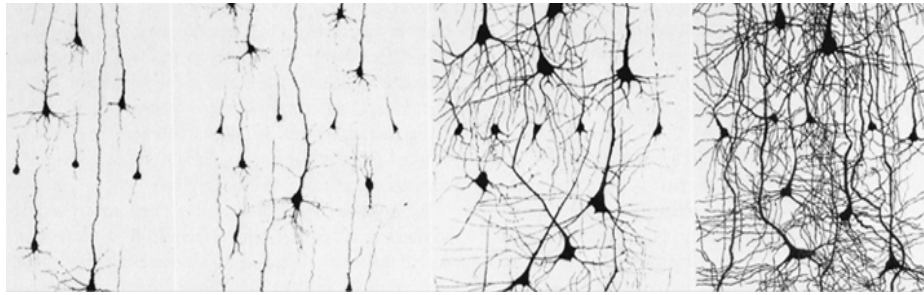


Figure reproduced with permission of MJ Dubin, MD, PhD, Weill Cornell Medical College
Liston C, et al. (2014). Default Mode Network mechanisms of Transcranial magnetic Stimulation in Depression. *Biol Psychiatry*.

Theory of Neuroplasticity



Unstimulated

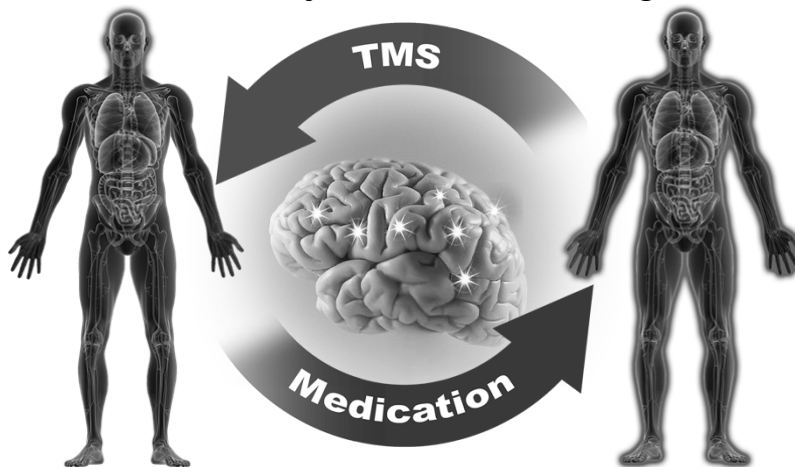
Stimulated

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Treating the Brain as an Electrochemical Target

Brain activity can be altered through:



TMS: is focused,
non-invasive & non-systemic

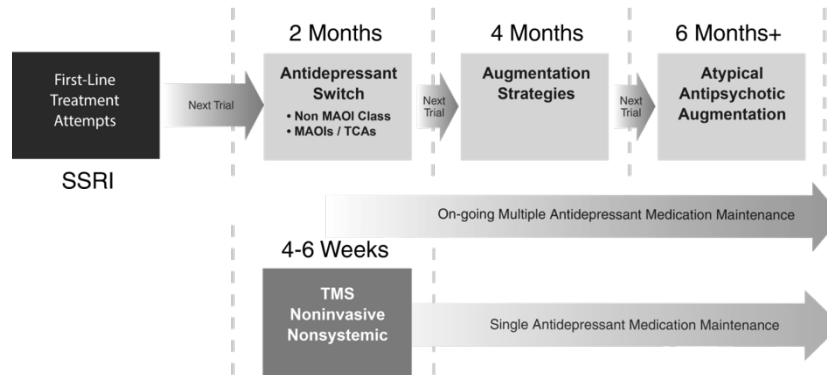
DRUG THERAPY: Action is
anatomically **diffuse** and systemic

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Best Practices Treatment Guideline for Depression

Based on 2010 APA guidelines and NeuroStar TMS Therapy® indication for use.



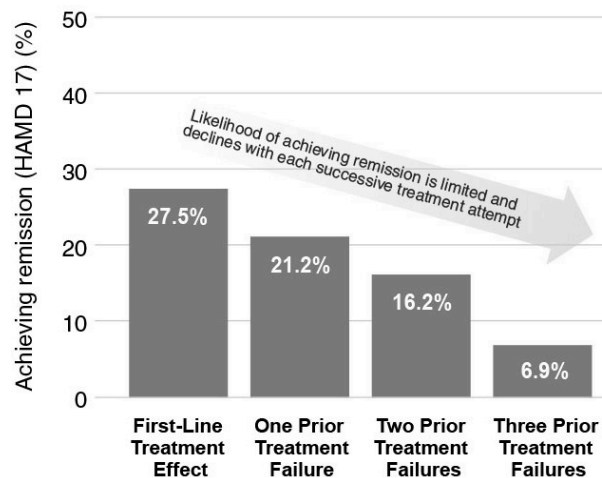
Adapted from: Practice Guideline for the Treatment of Patients with Major Depressive Disorder, 3rd Edition, APA (2010)

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STAR*D Study

demonstrates that current treatment has limited effectiveness

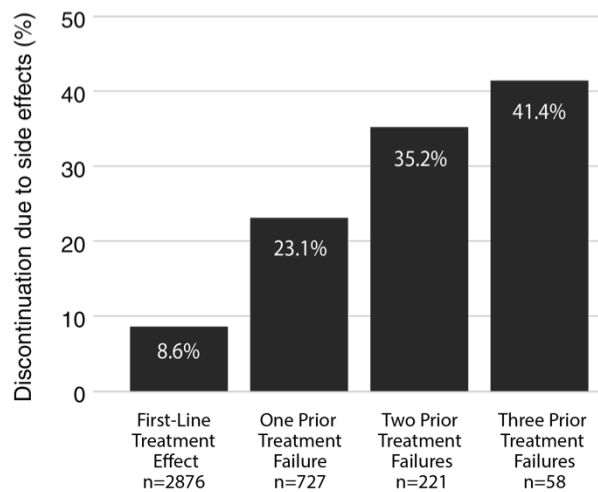


Trivedi (2006) Am J Psychiatry | Rush (2006) Am J Psychiatry | Fava (2006) Am J Psychiatry | McGrath (2006) Am J Psychiatry

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NEURONETICS

Likelihood of discontinuing treatment increases with each new medication attempt




Trivedi (2006) Am J Psychiatry | Rush (2006) Am J Psychiatry | Fava (2006) Am J Psychiatry | McGrath (2006) Am J Psychiatry
Neuronetics, Inc. (data on file)

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NEURONETICS

TMS Therapy Avoids the System Side Effects Commonly Experienced with Antidepressant Medications



TMS Side Effects

- ☐ Scalp Pain or Discomfort at Treatment Site

Systemic Drug Side Effects

<input type="checkbox"/> Weight Gain	<input type="checkbox"/> Nervousness	<input type="checkbox"/> Weakness	<input type="checkbox"/> Abnormal Ejaculation
<input type="checkbox"/> Constipation	<input type="checkbox"/> Anxiety	<input type="checkbox"/> Dry Mouth	<input type="checkbox"/> Impotence
<input type="checkbox"/> Diarrhea	<input type="checkbox"/> Increased Appetite	<input type="checkbox"/> Dizziness	<input type="checkbox"/> Sweating
<input type="checkbox"/> Nausea	<input type="checkbox"/> Decreased Appetite	<input type="checkbox"/> Fatigue	<input type="checkbox"/> Tremor
<input type="checkbox"/> Drowsiness	<input type="checkbox"/> Decreased Sexual Interest	<input type="checkbox"/> Headache/Migraine	<input type="checkbox"/> Treatment Discontinuation Side Effects
<input type="checkbox"/> Insomnia			

Adverse Events occurring at an incidence >5% and 2x the rate of placebo treatment

Janicak, et al. Transcranial Magnetic Stimulation in the treatment of major depression: A comprehensive summary of safety experience from acute exposure, extended exposure, and during reintroduction treatment. J Clin Psychiatry, 2008; Neuronetics, Inc., data on file.

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Primary Differences: TMS vs ECT

TMS

- Non-invasive
- Minimal Side Effects
- No Seizure
- Active participant during the session
- Brief Interruption in one's day

ECT

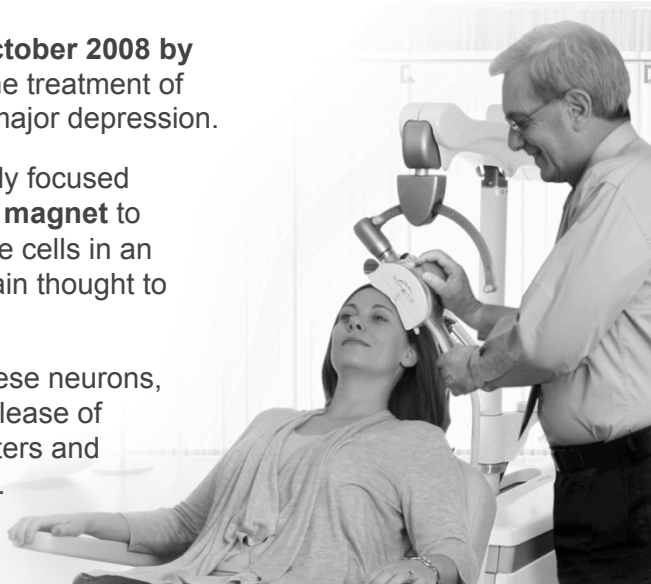
- Invasive
- Significant Risk of Side Effects
- Seizure Required
- Anesthesia Required
- Cannot Drive afterwards

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NeuroStar TMS Therapy® System

- **Cleared in October 2008 by the FDA** for the treatment of patients with major depression.
- Utilizes a highly focused **MRI-strength magnet** to stimulate nerve cells in an area of the brain thought to control mood.
- Stimulating these neurons, causing the release of neurotransmitters and clinical effects.

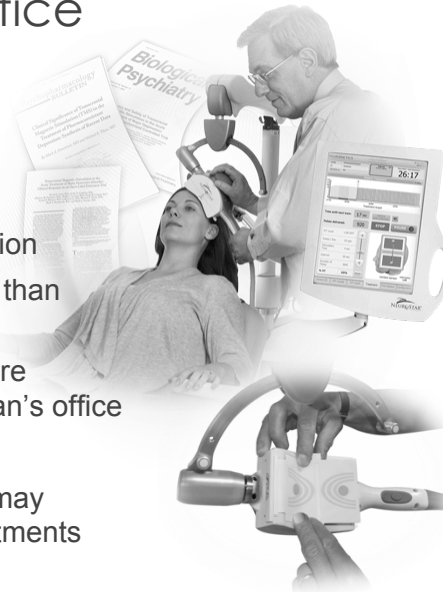


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TMS in Clinical Practice

- Non-invasive
- No anesthesia or sedation
- No systemic side effects
- No negative impact on cognition
- Tolerable treatment with less than 5% discontinuation rate
- 37 minute outpatient procedure easily performed in a physician's office
- 6 week treatment course
- Antidepressant medications may still be used during TMS treatments



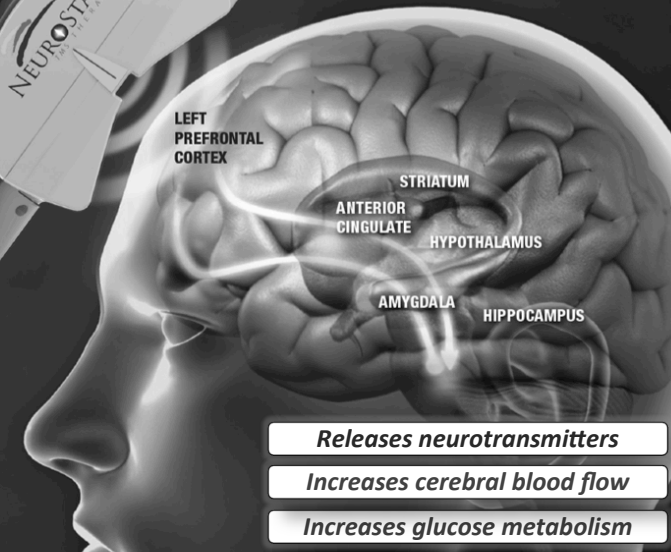
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PATENTED IRON CORE COIL

Precision Pulse TMS® Technology

- Targeted stimulation of the prefrontal cortex that activates deeper brain regions
- Flexible product design allows for high volume clinical use across a broad range of depression patient profiles



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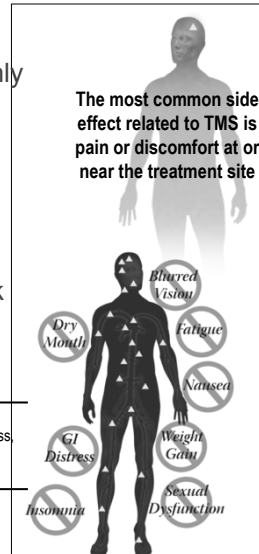
NEURONETICS

Proven Safety and Tolerability Profile

- Non-systemic, avoids the side effects commonly associated with antidepressant medications
 - » No adverse effect on cognition
 - » No adverse effect on sleep
- Excellent treatment adherence with less than 5% discontinuation rate due to adverse events
- Post marketing experience confirms a rare risk of seizure with NeuroStar TMS (<0.1% per patient)

MEDICATIONS: Other adverse events are nervousness, weakness, abnormal ejaculation, constipation, anxiety, impotence, diarrhea, increased appetite, dizziness, sweating, decreased appetite, tremor, drowsiness, decreased sexual interest, headache/migraine, blurred vision, and treatment discontinuation side effects.

NEUROSTAR: Eye pain, toothache, muscle twitching, facial pain, pain of skin.



Janicak PG, et al. (2008). J Clin Psychiatry.
Product Labeling for currently marketed antidepressants (Neuronetics, Inc., data on file).

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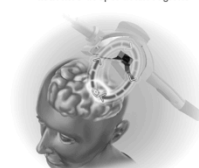
NeuroStar TMS Therapy® System

Precision Pulse TMS®

Patented Iron Core Coil
Efficiently transfers electrical energy into magnetic field for uninterrupted treatment



Precision Pulse TMS
Provides targeted stimulation of the prefrontal cortex that activates deeper brain regions



Gantry and Halo Supports the Treatment Coil and accurately maintains position throughout treatment, reducing the burden on the system operator

Iron Core Coil Designed for therapeutic use in multiple clinical practice settings

3D Coil Positioning System
Provides accurate and repeatable Treatment Coil position while providing the patient a comfortable head support



Treatment Chair
Provides comfortable patient seating during treatment sessions

Graphical User Interface
Intuitive system software guides system operator through step-by-step treatment workflow

MT Assist®
Unique software makes finding the right treatment dose easy

TMS TrakStar®

Patient Data Management System
Automatically captures all Motor Threshold and treatment information



Centralized Database
Manages all NeuroStar patient data

Custom Reports
Improves outcomes tracking

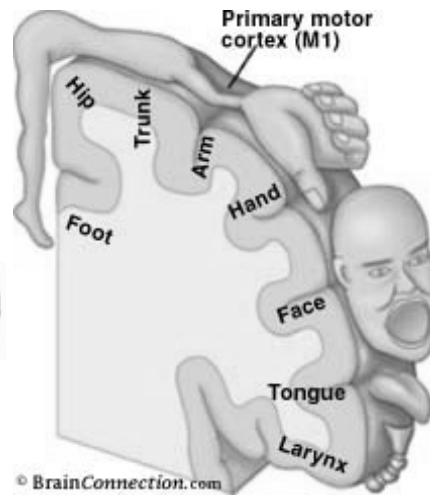
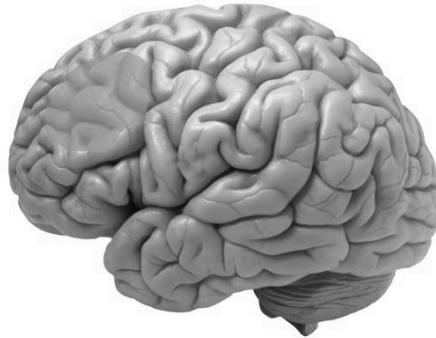
Web-enabled Technology
Accesses data from multiple systems and locations



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Individualized Treatment



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U.S. News & World Report
usnews.com

"...the use of an electromagnet to treat severe depression deserves a term that researchers hate to use: **breakthrough.**"

Transcranial Magnetic Stimulation: A Cure for Depression? Pt 1



THE DR. **OZ** SHOW



TIME
Global Business

10 Start-Ups That Will Change Your Life

Meet some of the World Economic Forum's Technology Pioneers—and the innovations they are bringing to market



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Top Behavioral Health Hospitals Provide TMS Therapy

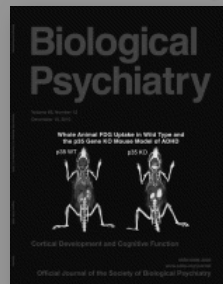
- Johns Hopkins Hospital
- Mayo Clinic
- McLean Hospital, Belmont, Mass.
- New York-Presbyterian University Hospital of Columbia and Cornell
- UCLA Semel Institute for Neuroscience & Human Behavior
- McLean Hospital
- Sheppard and Enoch Pratt Hospital



Proven Efficacy Demonstrated Through Randomized Controlled Trials

Efficacy and Safety of Transcranial Magnetic Stimulation in the Acute Treatment of Major Depression:

A Multisite Randomized Controlled Trial



Daily Left Prefrontal Transcranial Magnetic Stimulation Therapy for Major Depressive Disorder:

A Sham-Controlled Randomized Trial

Sponsored by the National Institute of Mental Health (NIMH)

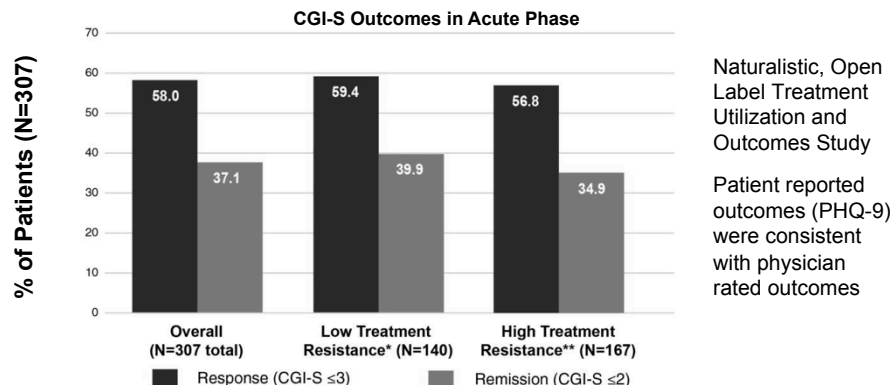


In an NIMH-funded, independent, randomized controlled trial, patients treated with TMS using the NeuroStar TMS System were **four** times more likely to achieve remission compared to patients receiving sham treatment ($P = 0.0173$, odds ratio = 4.05)

O'Reardon, et al. (2007) *Biological Psychiatry*; George, et al. (2010) *Arch Gen Psychiatry*

Consistent Response and Remission Rates Across a Broad Range of Treatment Resistance

1 in 2 Patients Respond, 1 in 3 Patients Achieve Remission



LOCF Analysis of intent-to-treat population

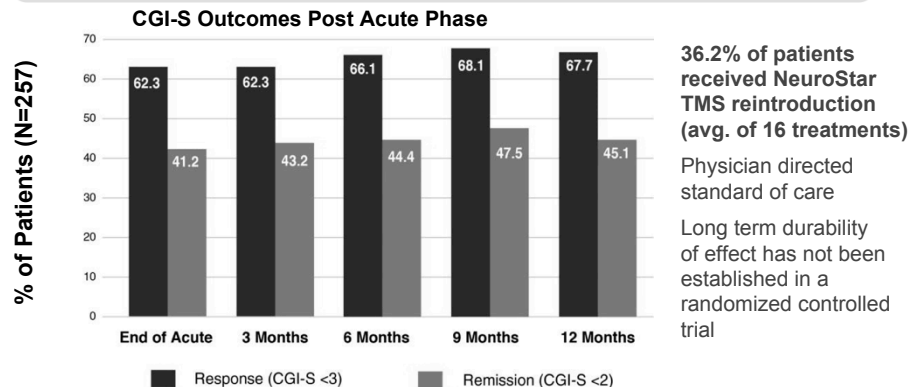
*0-1 adequate antidepressant medications; **≥2 adequate antidepressant medications
Carpenter, et al. (2012), Depression and Anxiety

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NeuroStar is the Only TMS System with Proven Durability Measured Over 12 Months

68% of study population in response, 45% in remission



LOCF Analysis of intent-to-treat population

Neuronetics, Data on file, NCT 00104611

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Areas of Ongoing Research in Investigator-Initiated Studies

Depression



- Adult depression
- Adolescent and teen depression
- Depression during pregnancy
- Postpartum depression
- Breast Cancer Patients With Depression and Anxiety
- Imaging Biomarkers for TMS Treatment of Depression
- Assessing brain response to rTMS in depression patients using simultaneous functional Near Infrared Spectroscopy (fNIRS)
- Predictive and response biomarkers of effective treatment with TMS for MDD

Pain



- Women with chronic widespread pain
- Pain and depression in patients with fibromyalgia
- Chronic neuropathic pain
- Role of the supraspinal opioidergic circuit in prefrontal rTMS induced analgesia

Anxiety



- Generalized anxiety disorder
- fMRI-guided TMS for generalized anxiety disorder

PTSD



- TMS for suicidal ideation PTSD

Tinnitus



- Tinnitus

Addiction



- Nicotine craving / smoking

Schizophrenia



- Auditory hallucinations in schizophrenia

Other

- Testing TMS safety in presence of surgical clips
- Near Infrared Spectroscopy (NIRS) to Investigate rTMS

Limited to investigational use in these areas. Investigators are responsible for ensuring clinical protocols have been reviewed by an Institutional Review Board and meet applicable regulatory requirements for investigational use.

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TMS Therapy: Real World Outcomes

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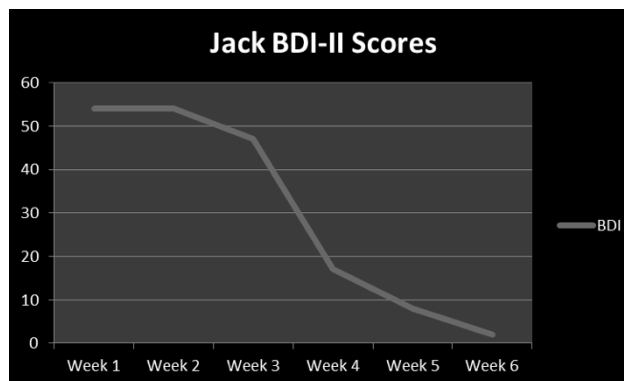
Case Study: Jack

Jack is a 60-year-old male referred by his psychiatrist. He has a history of depression that dates back to 1998. He was hospitalized in Fort Collins, Colorado. He has been on medication and in counseling since essentially that time. He is diagnosed with PTSD, Major Depression and possible Bipolar 2 Disorder. Jack suffered sexual abuse and verbal abuse at the hands of his parents and other family members when he was a child. He was initially diagnosed with Major Depression and started on Prozac. This did not work for him. He remembers trying Wellbutrin and Paxil. Wellbutrin was not effective and Paxil gave him serious side effect. Throughout the years he has also been on Effexor, Cymbalta and Seroquel, with minimal to no efficacy. He has been on lithium for the last 13 years and Lamictal for approximately ten years. He took Namenda for about three months several months ago but this was not effective either.

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Jack: Progress over 6 weeks



"I'm not sure how many weeks its been [since I finished] maybe 4, but doing great. I wake up every day and stop and then say, I'm not depressed! I asked my wife if it's a sin to feel this good. Thanks for giving my life back!!!"
- Jack

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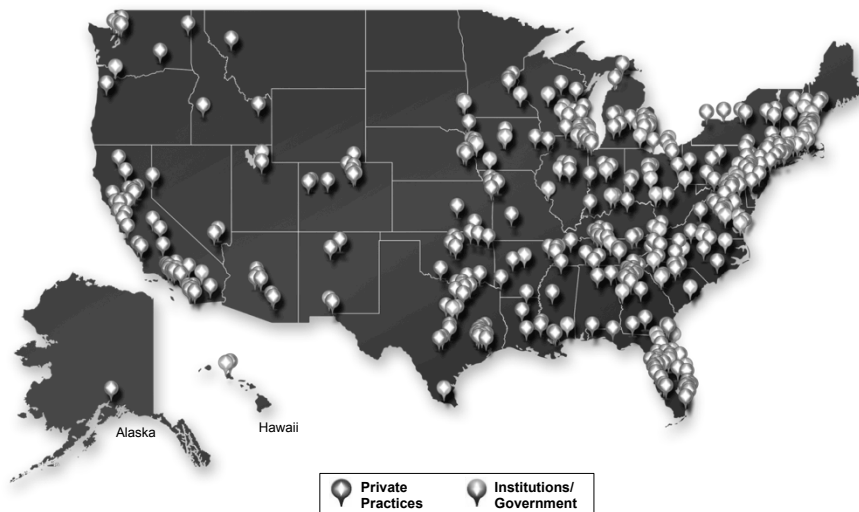
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Where Can I find Help?

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More than 650 NeuroStar® Locations
in the U.S.



Data compiled 07/01/15

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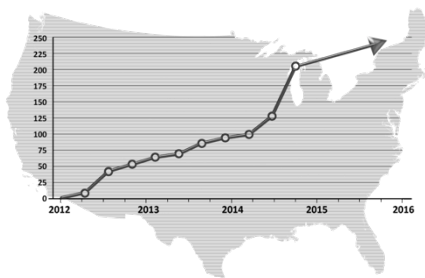
Does Insurance Cover the Cost of TMS?

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230M Covered Lives

As of 7/1/15



Anthem BCBS
BCBS of Alabama
BCBS of Arizona
BCBS of Florida
BCBS of Kansas
BCBS of Kansas City
BCBS of Louisiana
BCBS of Massachusetts
BCBS of Michigan
BCBS of Minnesota
BCBS of Nebraska
BCBS of Northeastern PA (NEPA)
BCBS of Rhode Island
BCBS of South Carolina
BCBS of Tennessee
BCBS Vermont
Blue Care Network
Blue Cross of Idaho
Blue Shield of California
BMC HealthNet
Cahaba Medicare
CareFirst Blue Cross
CommunityCare of Oklahoma
EmblemHealth
Fallon Community Health of Massachusetts
FEHP (Fed Blue)
First Coast Service Option
Harvard Pilgrim Health Care
Hawaii Medical Services Assoc

HCSC
Health Net
Health New England
Health Now
Health Plan of Nevada
Highmark BCBS
Horizon BCBS of New Jersey
Humana, Inc.
Independence Blue Cross
Kaiser Permanente Oregon
MVP Health Care
National Association of Letter Carriers
Neighborhood Health Plan MA
Neighborhood Health Plan of
Rhode Island Medicaid
NGS (Medicare)
Novitas Medicare JH
Novitas Medicare JL
Optima Behavioral Health
Optum/United Behavioral Health*
Palmetto GBA
Premiera Blue Cross
Priority Health
Rocky Mountain Health Plan*
Tufts Health Plan
UHC Community Plan (Medicaid of New England
UniCare (Massachusetts State Employees)
Vermont Medicaid
WA State HCA

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Madison Area Insurance Providers



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CPT® Category I Codes

90867

Therapeutic repetitive transcranial magnetic stimulation treatment; initial, including cortical mapping, motor threshold determination, delivery and management

90868

Subsequent delivery and management, per session

90869

Subsequent MT re-determination with delivery and management



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Source: Current Procedural Terminology 2013, American Medical Association
CPT is a Registered Trademark of the American Medical Association

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To schedule an appointment or for more information, contact:

TMS Center of Madison

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608.231.2200

www.connectionsounseling.com

a collaboration of



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together we recover

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www.TMSCenterhelp.com